

MAY 19 2000

EXHIBIT D  
K001119 Page 1 of 1

510(K) Summary

Submitter: Rovers Medical Devices BV  
Lekstraat 10  
5347 KV OSS  
The Netherlands  
PH +31 (0) 412 64 88 70  
FAX + 31 (0) 412 62 38 35

Contact Person: Meindert Zwart, President

USA Representative: Rovers Medical Devices  
960 Chapea Road  
Pasadena, California 91107  
PH (626) 744-9171  
FAX (626) 744-9182

Contact Person: Todd Gates

Device Name: Rovers EndoCervex Brush  
Common/Usual Name: Cervical Cell Sampler  
Classification Name: Cervical Cytological Endocervical Brush

Equivalent Device: Rovers Cervex-Brush

Device Description:

This device consists of a handle with a multi-bristled, soft plastic brush mounted on it. The bristles are intended to collect cervical cells for testing and evaluation. Its one-piece construction consists of polypropylene. It will be sold as a single-use, nonsterile disposable device.

Intended Use Statement:

The Rovers EndoCervex Brush is intended for the collection of cervical cells for analysis by Pap smear methods and / or by methods for detecting sexually transmitted disease (STD). The Rovers EndoCervex Brush should not be used after the first 10 weeks of gestation in pregnant patients.

Submitter's Statement

On behalf of Rovers Medical Devices, I, Todd Gates have reviewed the premarket notification, and believe that, to the best of my knowledge, all data and information contained in the 510(K) application are truthful and accurate, and that no material fact has been omitted.

Signature: Todd M. Gates Date: 5/2/00

Name: Todd M. Gates



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 19 2000

Mr. Todd M. Gates  
Rovers Medical Devices  
960 Chapea Road  
Pasadena, CA 91107

Re: K001119  
Rovers EndoCervex-Brush  
Dated: April 5, 2000  
Received: April 7, 2000  
Regulatory Class: II  
21 CFR §884.4530/Procode: 85 HHT

Dear Mr. Gates:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

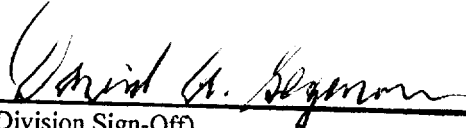
Enclosure(s)

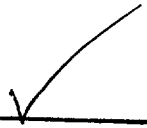
510(k) Number (if known): K001119

Device Name: Rovers EndoCervex-Brush

Indications for Use:

The Rovers EndoCervex-Brush is intended for the collection of cervical cells for analysis by Pap smear methods and / or by methods for detecting sexually transmitted disease (STD). The Rovers EndoCervex-Brush is not intended for use in pregnant women.

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K001119

Prescription Use   
(Per 21 CFR 801.109)